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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,881	04/21/2005	Sergey Kipriyanov	4121-172	6340

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INTELLECTUAL PROPERTY / TECHNOLOGY LAW
PO BOX 14329
RESEARCH TRIANGLE PARK, NC 27709

EXAMINER	
NATARAJAN, MEERA	
ART UNIT	PAPER NUMBER
1609	
MAIL DATE	DELIVERY MODE
05/01/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/510,881	KIPRIYANOV ET AL.	
	Examiner	Art Unit	
	Meera Natarajan Ph.D.	1609	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 April 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-28* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-17, 22, and 23 drawn to a combination of at least two antibodies comprising at least two different multivalent antibodies, an antigen binding domain specific to a tumor antigen, an antigen-binding domain specific to an antigen present on human T-cells, or an antigen-binding domain specific to an antigen present on CD3-epsilon negative human effector cells and a composition containing the combination of antibodies.

Group II, claim(s) 18-20 and 22, drawn to a polynucleotide encoding a combination of at least two antibodies characterized by the properties of claim 1, an expression vector, and a host cell containing said expression vector.

Group III, claim(s) 21, drawn to a process for the preparation of a combination of antibodies according to claim 1.

Group IV, claim(s) 24, 25 and 28, drawn to a method for treating B-cell malignancies, B-cell mediated autoimmune disease or the depletion of B-cells, the method comprising administering a therapeutically effective amount of a composition.

Group V, claim(s) 26 and 27, drawn to a gene therapy method for treating B-cell malignancies, B-cell mediated autoimmune diseases or the depletion of B-cells, the method comprising administering a therapeutically effective amount of the polynucleotides or expression vector.

The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or

corresponding special technical features for the following reasons: The technical featured recited in Claim 1 is a combination of at least two antibodies characterized by the properties stated above in Group I. Kipriyanov et al. (Int. J. Cancer 2001 – referenced in IDS cite no. AM) discloses a panel of bispecific antibodies with the dual specificity to human CD19 or CD30 on non-Hodgkin's or Hodgkin's lymphoma cells, respectively, and either to CD3, or CD28 or CD16 on human T cells or NK effector cells. It is widely known in the art that CD3 and CD28 are expressed on T cells, that CD16 is expressed on NK cells, i.e. CD3-epsilon negative cells, and that T cells and NK cells represent two different populations of effector cells. T cells and NK cells are the only effector cells mentioned in this document. A combination bispecific antibodies retargeting different populations of human effector cells towards the tumor was reported to significantly enhance the therapeutic effect. From this it is clear that a bispecific antibody with one specificity for a tumor antigen and the other for a T cell is combined with a bispecific antibody with one specificity for a tumor antigen and the other for an NK cell. Kipriyanov et al. teaches the technical feature recited in claim 1 and therefore it is not novel.

2. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows: Groups I-V involve a combination of at least two antibodies, where each is multivalent and binds both (1) a tumor antigen and (2) either a T cell antigen or an effector cell antigen. The claims further list two patentably distinct

species of tumor antigen, three patentably distinct species of T cell antigens, and four patentably distinct species of effector cell antigens. Therefore there are a large number of possible combinations, each requiring separate search. Applicant is directed to elect one specific combination, indicating the antigen species bound by each antibody in the combination. The species lack unity, because, as discussed above, the technical feature uniting the claims lacks novelty.

3. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: 6, 7, 14, and 15.

4. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the different antigens claimed will result in different antibodies directed towards specific binding regions, will effect binding ability, and antibody structure and function.

5. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Meera Natarajan Ph.D. whose telephone number is 571-

270-3058. The examiner can normally be reached on Monday-Thursday, 8:30AM-6:00PM, ALT. Friday. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mary Mosher can be reached on 571-272-0906. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MN

MARY MOSHER
SUPERVISORY PATENT EXAMINER

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4-25-07